K063547

SECTION 6 – 510(K) SUMMARY

Submitted by:	Witt Biomedical Corporation (a wholly owned subsidiary of Philips Holding USA, Inc.) 305 North Drive Phone: (321) 253-5693 Fax: (321) 253-0372
Contact Person:	James Luker
Date Prepared:	November 20, 2006 DEC 2 1 2006
Proprietary Name:	CALYSTO Series IV, Patient Care Monitor and Central Station System
Common Name:	Physio-monitoring and Information System
Classification Name:	21 CFR § 870.2300 74 MWI Monitor, Physiological, Patient (without Arrhythmia detection or alarms) Class II
Predicate Device:	CALYSTO Series IV, Patient Care Monitor and Central Station System K033030
Device Description:	The modified device has the same intended use as the legally marketed predicate device. It is intended to be used for complete physiologic/hemodynamic monitoring and information gathering. It facilitates clinical data acquisition and analytical assessment for cardiac catheterization, invasive radiology and electrophysiology laboratories.
Substantial Equivalence:	The modified CALYSTO Series IV System is substantially equivalent to the currently cleared CALYSTO Series IV System (K033030). Evidence of substantial equivalence is provided in section 10.
Intended Use:	The CALYSTO Series IV is intended for complete physiologic/hemodynamic monitoring, clinical data acquisition and analytical assessment for cardiac catheterization, invasive radiology and electrophysiology laboratories. Its users, responsible to interpret the data made available, will be professional health care providers. CALYSTO Series IV provides the ability to transmit patient data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device. Use of CALYSTO Series IV is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required. The CALYSTO Central Station and Patient Care Monitors are intended for complete physiologic monitoring, clinical data acquisition and analytical assessment within any healthcare environment. Its users, responsible to interpret the data made available, will be professional health care providers. User adjustable alarms (both visual and audible), alert the operator to anomalous occurrences and facilitate timely responses. Use of CALYSTO Central Station and Patient Care Monitors is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required. The CALYSTO Series IV ECG Management system is intended for

	receiving and storing resting, stress and holter ECG data from source devices. ECG data is stored, unaltered, in its original format, and made available for review and procedural report generation purposes. CALYSTO Series IV does not provide interpretive functions, but does store interpretive statements generated by the source device in an integrated and expandable database. Its users, responsible to interpret the data made available, will be professional health care providers. CALYSTO Series IV provides the ability to transmit ECG data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.
Technological Characteristics:	The modified device has the same technological characteristics as the legally marketed predicate device (K033030). The modifications consist of the implementation of the Respironics Capno 5 End Tidal CO2 mainstream and LoFlo sidestream End Tidal CO2 modules. In addition the Masimo MX-1 pulse oximetry module will be integrated with the current device as an option to the currently cleared Nellcor MP 506 pulse oximetry module. The specifications and accuracy of the proposed modules are equivalent to the currently legally marketed predicate device
Summary of Substantial Equivalence:	The modified CALYSTO Series IV system is substantially equivalent to the legally marketed predicate device. The modifications do not change the intended use or operating parameters of the system. No contraindications have been added or removed as a result of the modifications
Verification, Validation, and Testing:	Verification, validation and testing activities establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate. Pass/Fail criteria were based on the specifications cleared for the predicate device and the test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2006

Witt Biomedical Corp.
c/o James Luker
QA/RA Engineer
305 North Drive
Melbourne, FL 32934

Re: K063547
Trade Name: Calysto Series IV Physio-Monitoring and Information System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II
Product Code: MWI
Dated: November 24, 2006
Received: November 17, 2006

Dear Mr. Luker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5 –INDICATION FOR USE STATEMENT

510(k) Number:

Device Name: CALYSTO Series IV Physio-monitoring and Information System

The CALYSTO Series IV is intended for complete physiologic/hemodynamic monitoring, clinical data acquisition and analytical assessment for cardiac catheterization, invasive radiology and electrophysiology laboratories. Its users, responsible to interpret the data made available, will be professional health care providers. CALYSTO Series IV provides the ability to transmit patient data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.

Use of CALYSTO Series IV is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required.

The CALYSTO Central Station and Patient Care Monitors are intended for complete physiologic monitoring, clinical data acquisition and analytical assessment within any healthcare environment. Its users, responsible to interpret the data made available, will be professional health care providers. User adjustable alarms (both visual and audible), alert the operator to anomalous occurrences and facilitate timely responses.

Use of CALYSTO Central Station and Patient Care Monitors is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required.

Prescription Use __✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K04 3547